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EXAMINER

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 22

Application Number: 09/646,924

Filing Date: September 25, 2000

Appellant(s): RASPE ET AL.

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GROUP 2000

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Anthony J. Zelano
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed on May 6, 2003.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

Appellant's brief includes a statement that claims 1-22 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) *ClaimsAppealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) *Prior Art of Record*

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(10) *Grounds of Rejection*

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The current claims are drawn to a method for identifying a compound useful for the treatment of lipid metabolism dysfunction, which comprises a ROR receptor and its functional equivalents thereof. This large genus of functional equivalents of ROR receptor is represented in the specification by the broad term 'functional equivalents'. Thus, applicant has express possession of only one species, the ROR receptor itself, in a genus, which comprises hundreds of millions of different possibilities (such as ROR receptor equivalent having binding sites for compounds with antiarthritic and auto-immune activity). The written description guidelines note regarding such genus/species situations that "Satisfactory disclosure of a 'representative number' depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.) Here, no common elements or attributes of the ROR receptor functional equivalents are disclosed in the specification, which could give a clear definition of the functional equivalents. Further no information is given regarding a methodology to determine such common elements or attributes.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

In the instant application, the broadly claimed tub gene is not defined clearly. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

"...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

(11) *Response to Argument*

Appellants summarize case law on the written description requirement at pages 4-5 of the brief. The essential disagreement appears to be the interpretation of what constitutes the possession of a genus of ROR α receptor response elements thereof. The issue here is whether the specification adequately supports the large number of response elements of ROR α receptor by their structural limitations and function as required by the law.

It is noted in the recently decided case The Regents of the University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (Fed. Cir. 1997) decision by the CAFC that

"A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See Fiers, 984 F.2d at 1169- 71, 25 USPQ2d at 1605- 06 (discussing Amgen). It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. "

The instant invention is drawn to ROR receptors for screening substances useful for treatment of atherosclerosis with specific reference to ROR α receptor or a response element thereof involved in the regulation of the apo C-III gene. As described in the specification (page 1, lines 23-28), the ROR receptor exists in three forms. Each form binds to a specific response

element binding site, and modulate the transcription of their target genes. Further, the specification describes that ROR α receptors are involved in the regulation of the expression of the apo C-III gene.

Based on the above rejection Applicants amended the claims to recite the sub genus of ROR receptors, that is ROR α receptor and its target gene as apo C-III. The sub genus ROR α receptor itself comprises a broad family, which includes many other response elements other than the disclosed response element involved in the regulation of apo C-III. Each of these act via a different binding site(s) involved in the regulation of the target gene.

Thus applicants have shown one species of ROR α receptor and a fragment of response element that can interact with a substance to regulate the apo C-III gene. No information was given in the specification regarding the involvement of other response element(s) or its binding site(s) of ROR α receptor family, which regulate the expression of apo C-III gene. The response element as described in the specification consists of a fragment of apo C-III promoter positions between 1415 and +24. The specification did not describe where in this fragment the binding site and the biological function is situated that modulates the transcription of apo C-III gene. Further the said promoter region is a fragment of the said promoter. The specification described a fragment (a species) of the genus.

In analysis of the claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species situations that "Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the

species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.)

The current claims encompass a single species of a genus of ROR or ROR α receptor family. The genus includes response elements other than the specific fragment of a response element involved in the regulation of apo C-III target gene for which no written description is provided in the specification. The variation is permitted by the broad nature of claim 1 which is drawn to any response element of ROR α receptor family, which comprises many different response elements other than the specific fragment of response element recited in the instant amended claims.

Appellants argue that the issue "a response element thereof" is adequately defined in the instant specification as cited in the brief.

- (i) the response element consisting of the fragment of the apo C-III promoter (positions between 1415 and +24) defined by the specification merely is the same response element targeted to regulate the apo C-III gene;
- (ii) several copies of a response element created by a plasmid recognized by ROR receptor (includes all three forms of the ROR receptors) as described by M. Lazar are identified in the same apo C-III promoter region, and is merely the one and the same response element involved in the regulation of apo C-III gene.
- (iii) the construct RORETkCAT comprising a copy of the hROR α consensus site and the portions of consensus sequence sites in the human apo C-III promoter cited in the specification (as indicated in the brief), is the same response element or its fragments involved in the regulation of apo C-III gene.

All of the above apo C-III promoter consensus sequences encompass a single response element of ROR α involved in the regulation of apo C-III gene. Thus, applicant has expressed possession of only one species. The ROR α receptor as claimed is a genus, which comprises hundreds of millions of different response elements of ROR α receptor involved in regulating the target apo C-III gene.

The structural limitations as cited in the brief are drawn to a single response element involved in the regulation of apo C-III gene. There exists no support for other response elements of ROR α receptor as claimed for which no structural limitations or requirements are provided as a guidance for the identification of other response elements which meet these functional limitations.

In the current situation, the definition of structural limitation of a single particular response element targeted to regulate apo C-III gene is described. The genus is not described. The specific structure, is precisely the situation of naming a type of material which is generally known to likely exist, but, except for the specific examples given, in the absence of knowledge of the material composition and fails to provide descriptive support for the generic claim comprising several response elements of ROR α receptor. The structural features of a response element that could distinguish compounds or substances useful for the treatment of a lipid metabolism dysfunction are missing from the disclosure. No structural attributes identify the members of the genus. A single response element site for apo C-III alone is insufficient to describe the genus.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is

not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

The current situation is a definition of a response element of ROR α receptor the compound solely by its functional utility targeted to a particular gene, without any definition of any other response elements of ROR α receptor as claimed. One skilled in the art would reasonably conclude that the disclosure fails to provide a representation number of species to describe the genus. Thus Appellants were not in possession of the claimed genus.

In the instant application, specific response element is described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

"...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description, which would demonstrate conception of any response element binding site(s) and wherein the said region of the apo C-III promoter the biological function resides and binding sites for each of the many response elements as claimed.

Conclusion

Thus the claims fail to meet the written description requirement by encompassing response elements, which are not described in the specification. For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Suryaprabha Chunduru
Examiner
Art Unit 1637


Suryaprabha Chunduru
July 11, 2003

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